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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,408	07/02/2003	Michele Boix	17571 (AP)	4873

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EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
03/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/614,408	BOIX ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-26 and 70-87* is/are pending in the application.

4a) Of the above claim(s) *22-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9-24-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response, filed 1/16/2008 has been received. Claims 22 – 26 and 70 – 87 are pending, claims 22 - 26 are withdrawn, and claims 70 - 87 are treated on the merits below.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 70 – 72, 74 – 79, 81 – 83 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,835,139 to Tice.

The claims require a gamma irradiated therapeutic composition comprising microparticles, the microparticles comprising at least one polymer, which ultimately must be PLGA in claims 71, 72, and 79) , and at least one therapeutically active agent. The composition must be a sustained release composition in claims 77and 83, and the particles must have an average size of less than 100 microns in claims 78, 79 and 81 - 83. The composition is irradiated at 2.5 – 4.5Mrad in claims 74 and 81, and is "a freeze-dried powder" in claims 75 and 82.

Tice teaches microparticles comprising the active agent LH-RH analog, and PLGA copolymer (col. 1, lines 20-22). The microparticles are sterilized with gamma radiation between 2.5 and 2.8 Mrads (col. 3, lines 49 – 53), and are sustained release compositions, as they release their active agents over 25-30 days (col. 3, lines 40 - 43). The microparticles are between 30 and 50 microns in diameter (col. 3, lines 27 - 38). The particles are dried (Examples), which gives a product that is equivalent to the product obtained by the freeze drying step of instant claims 75 and 82.

Note that the claims also require that "the microparticles are less aggregated when gamma irradiated at less than 5 C than when the same therapeutic composition is gamma irradiated for the same time and at the same does of gamma irradiate at a temperature greater than 5 C." This is understood to be a property of the claimed PLGA particles. It would be expected that the PLGA microparticles of the art, which hav the same composition as instantly claimed particles, would also have this property.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive. Applicants argue that the reference does not disclose microparticles that are less aggregate when irradiated at temperatures less than 25C than at temperatures more than 25C. This argument is not understood, because the claims do not recite anything about microparticles that are less aggregate when irradiated at temperatures less than 25C than at temperatures more than 25C; the only temperature that the claims recite is 5C. Applicants also argue that the reference does not teach the beneficial qualities of lower irradiation temperatures, or the comparison of aggregated microparticles at irradiation temperatures less and greater than 25C. Again, this is not germane because the claims do not recite aggregation of microparticles at irradiation temperatures less and greater than 25C; the only temperature that the claims recite is 5C.

Even if "5 C" were substituted for "25 C" in Applicants remarks, the remarks would not be persuasive. Nothing in the claims actually requires that the microparticles be irradiated at less than 5 C. It appears that Applicants believe that they have

discovered a new property of PLGA microparticles, namely, that said microparticles are less aggregated when gamma irradiated at low temperatures. It is well established that recognizing a new property of an old product does not confer patentability on the old product, even if the newly recognized property is a particularly advantageous one. Accordingly, Applicants may not now patent, and thereby remove from the public domain, well known PGLA microspheres simply because Applicants have discovered a new property of said microspheres.

Claims 70 – 72, 75 – 80, 82 and 83 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,534,261 to Rodgers.

Roders teaches injectible microparticles of retinoids made from PLGA (col. 9, lines 10 – 15). The microparticles are sterilized by gamma radiation (col. 9, lines 30 – 33).

Note that the claims also require that "the microparticles are less aggregated when gamma irradiated at less than 5 C than when the same therapeutic composition is gamma irradiated for the same time and at the same does of gamma irradiate at a temperature greater than 5 C." This is understood to be a property of the claimed PLGA particles. It would be expected that the PLGA microparticles of the art, which hav the same composition as instantly claimed particles, would also have this property.

Claims 70 – 72, 74 - 79, and 81 - 83 are rejected under 35 U.S.C. 102(b) as being anticipated by Montanari (see PTO 892 mailed 8/9/2007).

Montanari teaches PLGA microspheres loaded with 15% CLO (the drug clonazepam) (abstract). The microparticles are irradiated at a dose of 25 kGy, which is

2.5 Mrads(2.5 Mrads at 1kGy = 0.1 Mrads) (abstract). The particles are lyophilized (section 2.1), and 90% of the micospheres have a size of 2 – 10 microns (section 3.1), so it is reasonable to conclude that the average size is less than 100 microns, as required by some of the instant claims.

Claims 70 – 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodgers in view of US 6,365,632 to Perricone and in further view of Tice and Montanari.

Some of the teachings of Rodgers have been discussed above. Rodgers also teaches particle sizes between 5 and 500 miconrs.

What is lacking is a teaching of tazarotene, the instantly claimed particle sizes, and the instantly claimed dosages of gamma irradiation.

Perricone teaches that tazarotene is a retinoid. Recall that Rodgers requires a retinoid active agent.

As discussed above, both Tice and Montanari teach particle sizes less than 100 microns as preferably for drug delivery. These references also teach dosages of radiation within the instantly claimed ranges. Also, these references teach different drugs that are useable in PLGA microspheres.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use tazarontene in the microspheres of Rodgers. Obviousness stems from the fact that Rodgers requires a retinoid, and tazarontene is a retinoid. Tice and Montanari go towards the reasonable expectation of success, because they teach that a variety of drugs can be used in PLGA microspheres.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use particle sizes less than 100 microns, since both Tice and Montanari prefer smaller particles. Because Rodgers includes particles as small as 5 microns, the artisan would enjoy a reasonable expectation of success.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use the irradiation dosages of instant claims. Rodgers is silent on what dosage is useful to sterilize particles, but Tice and Montanari teach the appropriate dosage. The artisan wishing to sterilize PLGA particles as Rodgers teaches would thus look to references such as Tice and Montanari, which teach appropriate dosages for sterilizing PLGA particles, and would enjoy a reasonable expectation of success when using those teachings.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive. Applicants argue that the reference does not disclose microparticles that are less aggregate when irradiated at temperatures less than 25C than at temperatures more than 25C. This argument is not understood, because the claims do not recite anything about microparticles that are less aggregate when irradiated at temperatures less than 25C than at temperatures more than 25C; the only temperature that the claims recite is 5C. Applicants also argue that the reference does not teach the beneficial qualities of lower irradiation temperatures, or the comparison of aggregated microparticles at irradiation temperatures less and greater than 25C. Again, this is not germane because

the claims do not recite aggregation of microparticles at irradiation temperatures less and greater than 25C; the only temperature that the claims recite is 5C.

Even if "5 C" were substituted for "25 C" in Applicants remarks, the remarks would not be persuasive. Nothing in the claims actually requires that the microparticles be irradiated at less than 5 C. It appears that Applicants believe that they have discovered a new property of PLGA microparticles, namely, that said microparticles are less aggregated when gamma irradiated at low temperatures. It is well established that recognizing a new property of an old product does not confer patentability on the old product, even if the newly recognized property is a particularly advantageous one. Accordingly, Applicants may not now patent, and thereby remove from the public domain, well known PGLA microspheres simply because Applicants have discovered a new property of said microspheres.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Eric E. Silverman, PhD
Art Unit 1618